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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,861	02/11/2000	CARLO RICCARDI	RICCARDI=1	7791

7590 03/19/2003

BROWDY AND NEIMARK  
624 NINTH STREET  
WASHINGTON, DC 20004

EXAMINER
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EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/19/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/403,861	<b>Applicant(s)</b> RICCARDI, CARLO	
	<b>Examiner</b> Janet L. Epps-Ford, Ph.D.	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-14-02 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 41-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 41, and those claims dependent thereon, recite a GILR protein encoded by the nucleotide sequence according to SEQ ID NO: 1 or by a nucleotide sequence capable of hybridizing with SEQ ID NO: 1, under stringent conditions.

The instant claims encompass a genus of proteins encoded by nucleotide sequences capable of hybridizing with SEQ ID NO: 1, under stringent conditions. The specification as

Art Unit: 1635

filed, page 25, lines 14-28, describe the DNA sequences encompassed by the claimed invention as capable of hybridizing with a cDNA sequence derived from the coding region of a native GILR protein, in which such hybridization is performed under moderately stringent conditions, and which encode a biologically active GILR protein.” (It is first noted that the instant claims do not recite that the conditions for hybridization are “moderately stringent” as set forth in the specification as filed.) Moreover, the specification as filed states that “these hybridizable DNA sequences therefore include DNA sequences which have a relatively high homology to the native GILR cDNA sequence and as such represent GILR-like sequences which may be for example, naturally-derived sequences encoding the various GILR isoforms, or naturally-occurring sequences encoding proteins belonging to a group of GILR-like sequences encoding a protein having the activity of GILR.” Furthermore, these sequences also include, “for example, sequences encoding analogs, fragments and derivatives of GILR, all of which have the activity of GILR.” (page 25, lines 14-28). Therefore, based upon the description of the claimed invention set forth in the specification as filed, the instantly claimed invention encompasses nucleic acid sequences “encoding analogs, fragments and derivatives of GILR, all of which have the activity of GILR.”

However, the specification as filed does not clearly provide a structural description of the full scope of nucleic acid sequences that are encompassed by the claimed invention, particularly wherein the nucleic acid sequence is capable of hybridizing under stringent conditions to SEQ ID NO: 1. Moreover, the specification as filed does not provide a description of the recited “stringent conditions” for hybridization, wherein such conditions would produce nucleic acid molecules that would encode proteins according to the present invention. It is also noted that

Art Unit: 1635

since the instant claims are not limited to any particular type of stringent conditions, i.e. low, moderate or high stringency, the instant claims broadly encompass nucleic acid sequences that are capable of hybridizing to SEQ ID NO: 1 under low, moderate, or highly stringent conditions, and that are capable of inhibiting apoptosis and stimulating lymphocyte activity.

Again, as stated in the prior office action, Applicant's specification does not sufficiently describe a clear nexus relationship between the amino acid structure of the GILR protein and the claimed functional limitations wherein the GILR protein is "capable of inhibiting apoptosis and stimulating lymphocyte activity." Applicants argue (page 2, paragraph 3 of "Remarks" submitted 8-14-02) that the sequence identity at the protein level between the mouse and human GILR proteins provide a description of where sequences are conserved and indeed provide a "clear nexus relationship" between the sequence, i.e., conserved regions, and the functional limitations. However, Applicants have not provided any functional evidence that only those conserved regions between the human and mouse proteins are responsible for rendering the protein capable of inhibiting apoptosis and stimulating lymphocyte activity. The skilled artisan would have to resort to trial and error experimentation in order to identify those nucleic acid sequences that are capable of hybridizing to SEQ ID NO: 1 under stringent conditions, and further test the proteins encoded by those sequences for their ability to inhibit apoptosis and to stimulate lymphocyte activity. Moreover, it is noted that the instant claims are not limited to only those proteins or nucleic acid sequences that comprise the conserved regions that were identified between the human and mouse GILR sequences.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written

Art Unit: 1635

Description" Requirement. These guidelines state that: "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention."

Applicants have not provided a sufficient structural description of the claimed invention that would allow one of skill in the art to envision the full scope of the claimed invention. In order to isolate the claim invention the skilled artisan must isolate nucleic acid molecules that hybridize to SEQ ID NO: 1 using stringent conditions that are not adequately described in the specification as filed, isolate the encoded polypeptide and test for its ability to inhibit apoptosis and stimulate lymphocyte activity. Nowhere in the written description guidelines does it provide for applicants to use a method of isolating a protein sequence and testing for the desired function, as a means for adequately describing an invention. The guidelines state that "[P]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention." In the instant case, other than the sequences that describe the mouse and human GILR proteins, one of skill in the art would not be able to immediately envision the structures of the full scope of compounds encompassed by the claimed genus without further experimentation.

Art Unit: 1635

The full scope of Applicant's claimed invention was not "ready for patenting" at the time of filing of the instant invention. Therefore applicants were not in possession of the full scope of the claimed GILR protein derivatives according to the present invention.

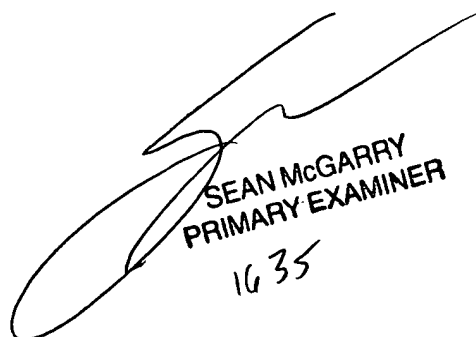
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
March 17, 2003

  
SEAN MCGARRY  
PRIMARY EXAMINER  
1635